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Comparing the benefits of applying a vacuum assisted lancing device in reducing lancing pain, improving self-monitoring frequency and reducing HbA1c in people with diabetes

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ABSTRACT

Background and aims: For most people with diabetes (PwD), lancing fingertips for obtaining a blood sample is unavoidable during blood glucose monitoring (BGM). This study investigated the potential benefits of applying a vacuum over the penetration site immediately, before, during, and after lancing to determine if a vacuum would allow a less painful lancing process from fingertips and alternate sites, while still drawing sufficient blood, thereby allowing PwD to have a painless lancing experience and improving self-monitoring frequency. The cohort was encouraged to use a commercially available vacuum assisted lancing device. Change in pain perception, testing frequency, HbA1c, and future probability of VALD use were determined.

Methods: In a 24-week randomized open-label, interventional, cross-over trial, 110 PwD were recruited who used VALD and non-vacuum conventional lancing devices, for 12 weeks each. Percentage reduction in HbA1c, percentage BGM adherence, scores of pain perception, and probability of selecting VALD in the future were measured and compared.

Results: There was reduction in overall HbA1c values (mean ± SD), (from 9.01 ± 1.68% at baseline to 8.28 ± 1.66%) and individually in T1D (from 8.94 ± 1.77% to 8.25 ± 1.67%) and T2D (from 8.31 ± 1.17% to 8.59 ± 1.30) after using VALD for 12 weeks. Lower pain perception and high probability of using VALD over conventional devices were observed.

Conclusion: The study highlights the benefits of applying a vacuum to the lance site which enhances the effectiveness in reducing and eliminating pain, improving self-monitoring frequency, and lowering HbA1c over non-vacuum conventional devices.

1. Introduction

According to the International Diabetes Federation, approximately 537 million adults (20–79 years) are living with diabetes mellitus [1]. Out of this, 5–10% have Type 1 diabetes (T1D) which mainly affects children and young adults and about 90% have Type 2 diabetes (T2D) seen more frequently in older people [1]. Persons with uncontrolled T2D and all persons with T1D administer regular subcutaneous insulin injections for the management of diabetes to prevent immediate and long-term complications [2–4]. For people who are on insulin, regular and routine blood glucose monitoring is mandatory, as this helps in maintaining good glycemic control and improves dietary habits to prevent complications like hypoglycemia.

Blood glucose monitoring (BGM) is the process of blood glucose testing by people with diabetes at home, school, work, or elsewhere [1]. BGM helps people with diabetes and their healthcare providers to monitor fluctuations in blood glucose and make appropriate treatment modifications. Monitoring frequency varies from six times a day for T1D to twice a week for T2D. Any impediments in the BGM monitoring frequency have been invariably associated with diabetes complications [5–9]. There is human resistance, especially in children, in conducting BGM practices routinely, due to the pain associated with finger pricking and squeezing [10,11].

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This pain is heavily associated with the needle type, anatomical site of lancing, lancing technique, and lancing depth [12,13]. Though mechanical lancers have improved in 25 years, they are extremely uncomfortable in day-to-day life [14,15].

In attempts to reduce the pain and improve BGM adherence, several studies have suggested less painful lancing methods. Few have suggested the use of alternate sites, such as the forearm, thighs, abdominal skin, earlobe, and back of the finger, which, however, had low precision and adaption [16–20], However, a Bayer device, Vaculance, introduced several decades ago was used by PwD for lancing. But the device is withdrawn from the market. The product now available for sale was the old inventory. Even though Vaculance uses a vacuum, and could draw blood from anywhere on the body using a special cap, its poor acceptance among users was because of the following reasons: It was painful to use, complicated, and required excessive manual dexterity so only those with extreme flexibility could make it work and left big red rings on the body on usage [21].

Though there are instruments claiming to deliver painless pricking in the market, most either give a superficial prick or use lancets with a small diameter measuring blood glucose from small blood volumes. Additionally, it has previously been established that increased testing frequency leads to a drop in HbA1c (glycohemoglobin) [22,23].

The aim of this study is to investigate the efficacy of using the principles of applying a vacuum lancing in reducing pain, encouraging more frequent testing, and leading to a reduction of HbA1c in persons with type 1 and type 2 diabetes after using it for 12 weeks. The device chosen to generate a vacuum is Genteel.

Genteel is a vacuum assisted lancing device (VALD) that automatically and immediately applies vacuum to the site before, during, and after lancing, thereby accelerating blood draw. The vacuum created by VALD allows the lancet to reach just the capillaries beneath the skin without damaging the adjacent tissues, such as pain nerves [24]. The Butterfly Touch Lancet (BTL) used along with the VALD device has a tri-beveled angled tip ranging from 30 to 36 gauge made of extremely rigid and smooth stainless steel needle with a base [25].

This study also aims to measure the percentage of BGM adherence and reduction in pain perception after using VALD for 12 weeks respectively. Additionally, the subjects were also asked about the likelihood of using the device, if available for routine BGM practice, in the future.

2. Materials and methods

2.1. Study population

Persons diagnosed with T1D or T2D aged ≤70 years and presented with uncontrolled glycemic status (HbA1c >8.0%) were included in the study. Minor subjects (<18 years) were accompanied by their caretakers. The study included only those persons with diabetes who were willing for BGM which included expert training to use both the VALD and the conventional lancing devices (CLDs) properly.

Persons with diabetes who were more than 70 years and less than 5 years with an HbA1c less than 8%, participants of other clinical studies, PwD showed unwillingness for BGM, mental incapability, severe liver, and kidney dysfunction, diabetic retinopathy and neuropathy, cardiac complications, and cancer, pregnant, breastfeeding women and women planning for pregnancy were excluded from the analysis.

2.2. Study design

This was a randomized open-label, interventional, cross-over trial to assess the benefits of immediately applying vacuum to the test site as mechanized by VALD's (Genteel LLC, Tualatin Oregon) technology (Fig. 2) over CLDs (On call plus, Contour, One Touch Verio Flex, Accu-check), in improving self-monitoring frequency and HbA1c. The trial was conducted from February 2nd, 2020 to August 31st, 2021 at Jothydev's Diabetes and Research Centre, Trivandrum, Kerala, India. The study protocol (NCT04214704) was approved by the regulatory authorities and the ethics committee of the centre. The study was conducted in accordance with the Declaration of Helsinki and the International Conference on Harmonization Good Clinical Practice guidelines. Informed consent was taken from all selected candidates prior to their study participation.

A total of 110 persons with diabetes were recruited for the study. Crossover AB/BA design was used for randomization, where the study cohort included in the GC (G for Genteel and C for conventional) used VALD for the first 12 weeks and switched to the CLD method of BGM in the next 12 weeks. For those in the CG group, the procedure was reversed. Each group recruited around 55 subjects to account for a 10% attrition rate. Fig. 1 summarizes the study protocol. Butterfly Touch Lancets were used with the VALD throughout the study. CLDs and lancets were those used prior to the randomization.

1. The frequency of BGM was 4-point BGM, twice weekly for people with T2D and 6-point BGM daily for people with T1D, throughout the study. Both the study groups used the same glucometer for uniformity. Physical visit to the centre was scheduled in 12 and 24 weeks after study initiation and phone visits were made based on the monitoring frequency for T1D and T2D. The subjects were trained to use the glucometers for self-assessment prior to trial initiation and were instructed to record the BGM values along with the details on the site of injection and contact tip used. During the physical visit to the study centre, the following assessments were done. Cross-checked the glucometer memory with the
   1. Recorded BGM values
   2. Reviewed device usage by the subjects
   3. Subjectively assessed the pain
   4. Evaluated patient diary bearing details on the sites of injection and the Contact Tip used (lancing depth).

The site of blood draw while using VALD included finger, palm, forearm, toe, thigh, shoulder and abdomen. However, due to the difficulty, without vacuum assist, of reliably getting sufficient test blood from alternate sites only fingerpricks were used to withdraw blood using the non-vacuum CLD. The injection site and color of the ContactTip (blue, yellow, green, clear, orange, and violet) recorded while using VALD were as per the subject's preference. The color of the Contact Tip relates to the depth of penetration, with blue the shallowest, progressing to violet being the deepest in 0.025' (0.64 mm) increments. Users of conventional lancers set the depth of penetration in a conventional way as per the instructions for use of their lancers.

2.3. Subjective assessment of pain before trial initiation

The perceived pain assessment was done using the 4-point pain screening questionnaire, which gives a preliminary assessment of the pain tolerance of the subjects during the time of screening

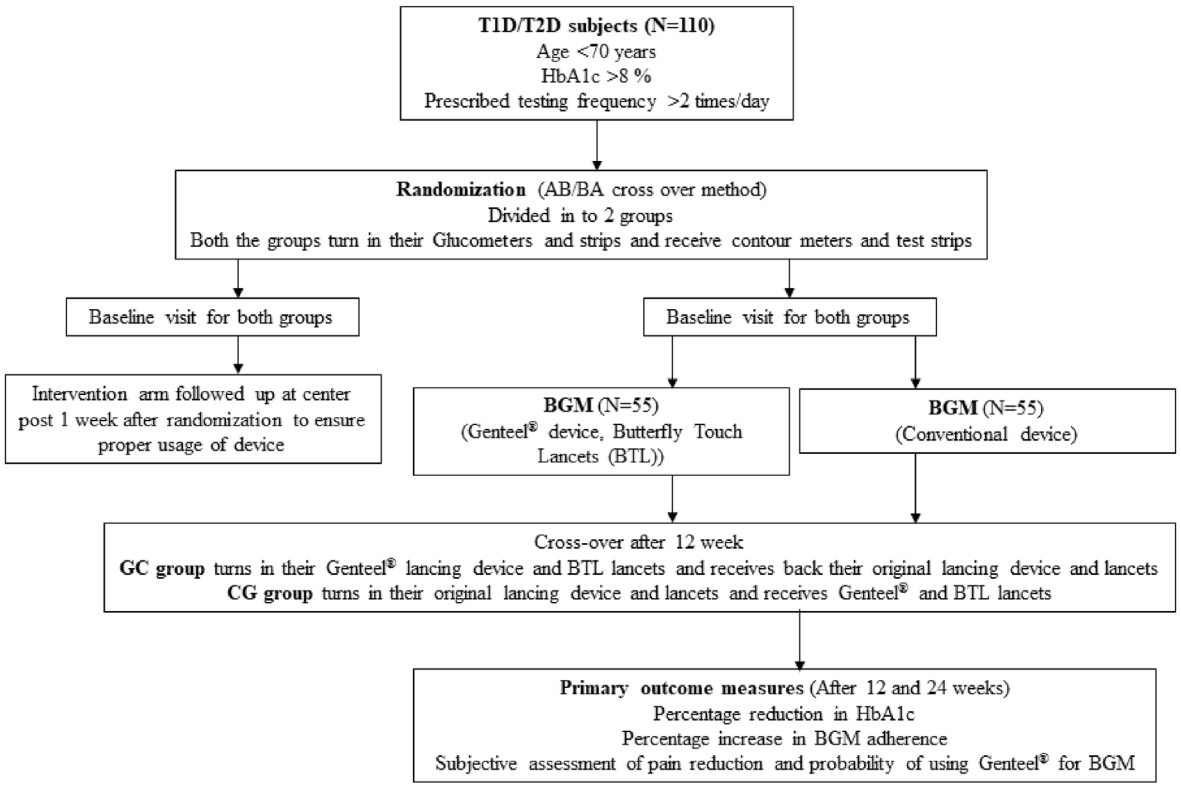


Fig. 1. Diagrammatic representation of study protocol.
BGM represents Self-Monitoring of Blood Glucose, HbA1c is glycohemoglobin, GC group represents Genteel-Conventional group and CG group represents Conventional-Genteel group, T1D is Type 1 diabetes mellitus and T2D is Type 2 diabetes mellitus.

procedure prior to initiation of the trial. This numeric pain rating scale was customized in the study center. Participants answered the following questions from the questionnaire.

1. What is the extent of pain associated with pricks for BGM? (1- Very painful; 2- Painful; 3- Minimally painful; 4- Almost not painful; 5- Not at all painful).
2. What is the extent to which pain is a limiting factor for BGM? (1- Very strong limitation; 2- Strong limitation; 3- Possible limitation but does not affect BGM practice; 4- Not a limitation and does not affect BGM; 5- No pain associated with BGM).
3. If you had access to a new lancing device on the market for BGM, would you use it? (1- Very much in need; 2- In need and would prefer to use such a device; 3- No need of it, but would use one if available; 4- No need of it, and will not use one; 5- No pain at all during BGM so such a device is irrelevant).
4. How has BGM practice affected your quality of life? (1- Very significant impact on quality of life; 2- Has some negative impact on quality of life; 3- Negligible impact on quality of life; 4- Absolutely no impact on quality of life; 5- Irrelevant question as BGM is not a painful practice).

2.4. Primary outcome measures after trial initiation

The primary outcome measures included were the following:

1. Percentage BGM adherence: It is the percentage of total recorded BGM values as compared to the ideal number of readings over a period of 12 and 24 weeks.

BGM Adherence = Actual number of finger pricks/the ideal number of finger pricks

where,

Ideal number of finger pricks for T1D subjects is 6 times daily
Ideal number of finger pricks for T2D subjects is twice weekly

2. Percentage reduction in the HbA1c values as compared to the baseline values at 12 and 24 weeks.

2.5. Secondary outcome measures after trial initiation

Subjective assessment of pain reduction after using VALD for 12 weeks: The subject's subjective pain assessment was recorded using a customized numeric pain scale.

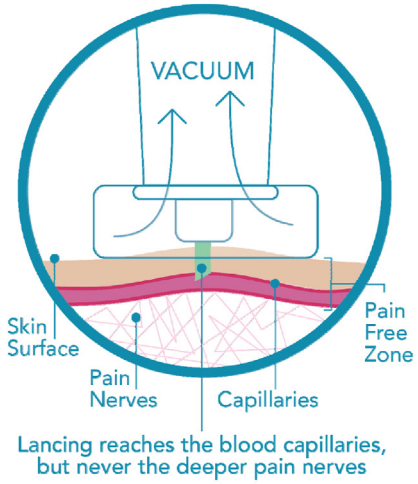
The scale used for assessing pain sensation included the following:

1. Elimination (1)
2. Significant reduction (2)
3. Slight reduction (3)
4. No change (4)
5. Mild worsening of pain (5)
6. Significant worsening of pain (6)

2.6. Subjective assessment of the probability of using VALD for BGM

The subjects were asked about the likelihood they would use the device, if available, for routine BGM practices in the future. The

Vacuum assisted lancing device (Genteel)



Working principle of VALD

Fig. 2. (a). Vacuum assisted lancing device (Genteel) **2(b).** Working principle of VALD.
(Source: https://www.hmsmedical.com.au/shop/veterinary/genteel-lancing-device-for-pets/)
Genteel is a VALD that automatically and immediately applies vacuum to the site before, during, and after lancing, thereby accelerating blood draw. The vacuum created by VALD allows the lancet to reach just the capillaries beneath the skin without damaging the adjacent tissues, such as pain nerves.

scale for predicting future (probability) use of the device for BGM is as follows:

1. Definitely yes (1)
2. Probably yes (2)
3. Not sure (3)
4. Probably no (4)
5. Definitely no (5)

2.7. Statistical analysis

All statistical analysis was done using the SPSS software, version 16. Percentage BGM adherence and percentage HbA1c reduction after using VALD were compared with that of the CLDs using paired *t*-test. Scores of pain scale and the probability of using VALD in the future scale were compared with that of the CLDs using Wilcoxon signed-rank test. A P-value of <0.05 was considered significant.

3. Results

3.1. Demographic variables

Out of the 110 persons with diabetes who participated in the trial, 60 were males and 50 were females. The average age of the sample population was 34.86 ± 21.31 years. Out of 110 participants, 58 (52.7%) had T1D and 52 (47.3%) had T2D. They were randomly and equally divided into two groups. Between groups, the subjective pain experienced by the persons with diabetes before trial initiation was not significantly different.

Of all the sites, the forearm was the most preferred among T1D (41.4%) and T2D (51.9%) subjects. Finger (22.7%) and palm (25.4%) were also preferred among the subjects. 77.2% of the study population preferred a place other than their finger to draw blood. Evidently, majority of the subjects (T1D: 65.5%; T2D: 53.9%; overall: 60.0%) found the yellow-colored Contact Tip most appropriate to withdraw a sufficient amount of blood for glucose monitoring with minimum pain.

3.2. Primary outcome measures

The percentage of BGM adherence was significantly higher in the VALD group in comparison to the conventional group in both T1D and T2D subjects and in the overall sample (Table 1). Overall, there was 44.1% increase in BMG adherence while using VALD over CLDs. Another advantage of a vacuum is that it stabilizes the skin position relative to the lancet trajectory so the lancing depth will be more consistent. The vacuum holding the tissue in place not only reduces the pressure wave but localizes it more and thereby reducing the pain associated with lancing. In the overall sample and in both the diabetes population, the percentage reduction in HbA1c from baseline was also found to be significantly higher when the subjects were using VALD in comparison to the CLDs. There was a reduction in the overall HbA1c values (mean ± SD, from 9.01 ± 1.68% at baseline to 8.28 ± 1.66%) in VALD users and individually in sub-populations-T1D, (from 8.94 ± 1.77% to

Table 1
Percentage BGM adherence while using VALD and CLDs.

Type	N	VALD (Mean ± SD) %	CLD (Mean ± SD) %	Increase from CLD (%)	p value
T1D	58	83.10 ± 10.74	77.82 ± 13.45	11.60	0.05*
T2D	52	78.44 ± 14.10	48.96 ± 18.43	80.43	0.000***
Overall	110	80.90 ± 12.60	64.18 ± 21.51	44.14	0.000***

T1D is Type 1 diabetes; T2D is Type 2 diabetes; BGM indicates Blood Glucose Monitoring. p value indicates significant difference between VALD and the CLDs (Paired *t*-test).

8.25 ± 1.67%) and T2D, (from 8.31 ± 1.17% to 8.59 ± 1.30%) after using vacuum over the lance site for 12 weeks. There was also observed a reduction in HbA1c values when using the CLD. However, the reduction was less compared to using VALD (Table 2). A 0.32% further reduction in HbA1c was observed when using VALD instead of their conventional lancing device.

3.3. Secondary outcome measures

Frequency distribution of the scores for the extent of pain reduction after using the lancing devices for 12 weeks and the probability of using these devices in the future revealed that 100% of the study population reported results from a reduction to the complete elimination of pain when using VALD. 75% of the VALD users reported either a significant pain reduction or the complete elimination of pain.

Table 3 shows the pain perception during BGM practices after 12 weeks. The VALD group observed a significant reduction in pain ($p = 0.000$) as indicated by a median score of 2. The median score for the conventional group was 4, which indicates no change in pain during BGM practices.

Furthermore, the probability of using the VALD to provide a vacuum over the lance site in the future was found to be significantly higher when compared to a CLD without a vacuum. The median score given by the T1D subjects was 1 (definitely use) for VALD and 3 (not sure) for the CLDs. Similarly, the score given by the subjects with T2D and the overall sample was 2 (probably yes) for VALD and 3 (not sure) for the CLDs. No data on hypoglycemia was collected as it was outside the purview of the study.

All patients who were included in the trial stuck to the regimen till 12 weeks. Among the T1D cohort who performed conventional lancing, only 3.45% missed >50% of the total number of pricks in the CG arm. Similarly in the GC arm, 6.9% missed >50% of the total number of pricks. Among the T1D cohort who used VALD, none of them missed >50% of the total number of pricks in both CG and GC arms.

4. Discussion

During BGM practices designed to simulate typical home use, the lancing device, VALD was found to be superior in aspects of pain reduction, testing adherence, and lowering HbA1c in comparison to CLDs. The results highlight that BGM adherence was 44% higher in subjects who used VALD. Evidently, increased lancing frequency facilitated by VALD and its alternate site testing ability to apply vacuum might have contributed to improved BMG adherence, lowered HbA1c and reduced pain perception. Moreover, VALD's ability to use alternate site testing and reliable blood draw can eliminate sore fingers and associated tissue damage. While alternate sites have less pain nerves than fingers, prior to the use of vacuum, AST has not had success as a pain reduction method because sufficient blood could not be reliably drawn without quite deep penetration [26].

Reasonably, majority of the subjects were sure to switch to the VALD technology if available for BGM practice in the future. With the help of vacuum technology used in VALD· and its choice of six different Contact Tips, penetration of the lancet is controlled, and the vacuum, securing the skin in a consistent fixed place against the Contact Tip, leads to more reliable penetration depth for the lance trajectory. Due to intra-and inter-individual differences in the choice of contact tip, the depth of lancing was not quantified in this study. Nevertheless, this device provided the subjects with various options to choose an optimum lancing depth based on their perceived pain and amount of blood from the site.

There is a high correlation between reduced blood glucose measurement frequency and suboptimal metabolic control (i.e., high levels of HbA1c) [12,27]. Hence, higher BGM adherence and associated frequency of lancing while using the VALD would have contributed to lower levels of HbA1c in the study cohort. Routine and systematic monitoring of blood glucose levels are highly important in maintaining glycemic control and preventing diabetes complications [5–8].

5. Clinical relevance of the study

Self-monitoring of glucose is an inevitable part of diabetes management. Among the various limiting factors towards efficient self-monitoring of blood glucose, pain associated with pricking can be considered a key element and it has been perceived as a major impediment to the self-monitoring of blood glucose. The VALD offers a painless pricking experience thus augmenting the frequency of blood sugar monitoring which contributes to more efficient and effective diabetes management. This interventional study conducted in 110 subjects, revealed that higher BGM adherence and associated frequency of lancing using VALD would have contributed to lower levels of HbA1c. A greater reduction of 0.32% in HbA1c was observed when using VALD compared to CLDs.

A significant number of subjects expressed their willingness to

Table 2
Absolute HbA1c and the percentage reduction in HbA1c from baseline after using VALD and CLDs.

	Baseline HbA1 (Mean ± SD) %	HbA1c using VALD (Mean ± SD) %	Overall reduction from baseline (%) while using VALD	HbA1c using CLD (Mean ± SD) %	Overall reduction from baseline (%) while using CLD	p value
T1D	8.94 ± 1.77	8.25 ± 1.67	0.69	8.60 ± 1.28	0.34	0.0262*
T2D	9.08 ± 1.59	8.31 ± 1.17	0.78	8.59 ± 1.30	0.49	0.0145*
Overall	9.01 ± 1.68	8.28 ± 1.66	0.73	8.60 ± 1.29	0.41	0.0013*

T1D is Type 1 diabetes mellitus; T2D is Type 2 diabetes mellitus; HbA1c indicates glycohemoglobin. p value indicates significant difference between VALD and the CLDs.(Paired *t*-test).

Table 3
Pain perception during BGM practices after using VALD and the probability of using VALD in the future.

	Type	N	VALD	CLD	p value
Pain perception during BGM practices (6-point scale)	T1D	58	2 (1, 3)	4 (3, 5)	0.000***
	T2D	52	2 (1, 3)	4 (2, 5)	0.000***
	Overall	110	2 (1, 3)	4 (2, 5)	0.000***
Probability of using the lancing device in the future (5-point scale)	T1D	58	1 (1, 4)	3 (2, 4)	0.000***
	T2D	52	2 (1, 4)	3 (1, 4)	0.000***
	Overall	110	2 (1, 4)	3 (1, 4)	0.000***

T1D is Type 1 diabetes mellitus; T2D is Type 2 diabetes mellitus; BGM indicates Blood Glucose Monitoring.Values are represented as Median (Min, Max); p value indicate significant difference between VALD and the CLDs (Wilcoxon-signed rank test).

continue VALD, even after the study period. 79% of subjects in the study reported either elimination of pain or a significant reduction in pain after using VALD for 12 weeks.

6. Limitations of the study

The subjects on VALD used butterfly lancets during the entire study period whereas the subjects on conventional lancers were using different lancets available in the market. This can be considered a potential bias in addition to the fact that the assessment of pain is a subjective measurement.

7. Conclusion

This clinical study gives evidence on the benefits of applying a vacuum before, during, and after lancing among subjects with diabetes in reducing and eliminating pain even when used on fingertips and allowing reliable blood draw from inherently less painful alternate sites. This led to improved self-monitoring frequency and lowered HbA1c when compared to non-vacuum CLDs. Increased self-monitoring or lancing frequency facilitated by VALD may have promoted the lowering of HbA1c. Reduction in pain and alternate site testing ability of VALD may have contributed to higher BGM adherence and frequency of lancing that subsequently contributed to lower levels of HbA1c.

Funding

This study received an investigator-initiated grant from Genteel LLC.

Institutional review board statement

The study was conducted as per the Declaration of Helsinki and the International Conference of Harmonization- Good Clinical Practice guidelines. Approval from the institutional review board was obtained, and the study was conducted in compliance with the protocol.

Informed consent statement

Informed consent was obtained from all patients/their guardians involved in the study.

Data availability statement

Request can be raised for de-identified data through the corresponding author.

Author contribution

JK conceptualized the study, JK, GBC, AS & GK conducted the study, JK, GK, & AS framed the methodology, JK, GBC, AB, GK, & AS validated and analyzed formally, AB & GK wrote & edited the manuscript, JK, GBC, GK, AB, AS & SJ contributed to the validation, review & edition of the manuscript.

Declaration of competing interest

The authors declare no conflict of interest regarding the manuscript.

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